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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Borje Sellergren

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EXAMINER

KOSAR, ANDREW D

ART UNIT

PAPER NUMBER

1654

MAIL DATE

DELIVERY MODE

06/11/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/707,990	Applicant(s) SELLERGREN ET AL.	
	Examiner Andrew D. Kosar	Art Unit 1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 6/28/06.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) 7-9 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 4/4/06 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments/Amendments

Applicant's arguments and amendments filed April 4, 2006 are acknowledged and have been fully considered. Any rejection and/or objection not specifically addressed below in original or modified form is herein withdrawn.

Election/Restrictions

Claims 7-9 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on October 7, 2005 and July 6, 2005.

Sequence Compliance

Applicant is advised that the application is not in compliance with 37 CFR §§ 1.821-1.825.

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR § 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR §§ 1.821-1.825 for the reason(s) set forth in the previous Office action. Specifically, although a withdrawn claim, Applicant has not amended claim 9 as required in the previous action. The tetrapeptide H-Phe-Gly-Gly-Phe-OH (claim 9) requires a sequence identifier.

Drawings

The drawings are objected to because Applicant has provided only the amended drawing. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. **Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even**

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if only one figure is being amended (emphasis added). The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 4 remains rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicant argues that the term ‘peptide’ is broadly intended to encompass one or more amino acids, and thus the claim is definite. Respectfully, such interpretation is contrary to the widely accepted use of the term in the peptide arts. Peptides are at minimum two amino acids, and any such interpretation that it can be a single amino acid is repugnant to the art. Applicant is suggested to amend the claims, including the independent claim, to recite an amino acid or a peptide, such that claim 4 would be properly dependent.

Claim 4 lacks clear antecedent basis. The claim recites a Markush group for the 'peptide', however many of the members of the Markush group are not peptides, but rather modified single amino acids. Thus, claim 1 does not provide support for the compounds which are not at least dipeptides. Further, it is unclear how one 'synthesizes' a peptide of a single amino acid, as attachment of a protected amino acid is not synthesis, but rather 'attachment' to the support.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 5 and 6 remain rejected under 35 U.S.C. 102(b) as being anticipated by MOSBACH (US Patent 6,489,418 B1).

The instant claims are drawn to synthesis of a molecularly-imprinted material (MIM), also known in the art as molecularly-imprinted polymers (MIP), comprising the steps of binding the peptide to a surface modified support, polymerizing monomers, e.g. acrylamides and/or methacrylates, using heat, UV, or a crosslinking agent, e.g. AIBN, and removing the support/peptide (dissolve/degrade) to generate the free MIM.

Applicant argues that Mosbach does not teach synthesis of a peptide on the support, but rather teaches attachment of a peptide to a support, and thus cannot anticipate the claims. Respectfully, the examiner disagrees. Applicant considers 'synthesizing a peptide' to include attachment of an amino acid, which by virtue cannot be considered by the artisan to be 'synthesis', but would always be considered attachment. However, given that Applicant includes attachment of a single amino acid to the support as being 'synthesis', the examiner under the

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broadest reasonable interpretation allowable in light of the specification, understands 'synthesis' to include attachment. Thus, attachment of the peptide in Mosbach is the same as 'synthesis' instantly used. Furthermore, as indicated in the previous Office Action, Applicant has admitted that all peptides are equivalent (paraphrased from statement under 35 USC § 103, below), thus 'synthesis' of a peptide consisting of one amino acid, where the only step is attaching to the support is no different than 'synthesis' where the peptide is any of those in Mosbach where the 'synthesis' is simply attachment.

Mosbach teaches a general synthesis of a MIM in Example 3 (column 5) where trypsin is immobilized on agarose beds, and monomers are polymerized with a crosslinker and the agarose beads are dissolved with addition of an acidic solution.

In Example 4 (column 5), Mosbach further teaches attachment of insulin to a surface-modified silica surface, which has been modified to have N-hydroxysuccinimide esters as pendant groups. Imprinting is conducted with either a methacrylate/ styrene/ acrylamide/ bisacrylamide solution with the photoinitiator being methylene blue, or with VBIDA, MAA and EGDMA with AIBN as the initiator. The imprint is "a stable film which can be separated from the surface on which it has been formed, e.g. manually or by dissolution." (column 5, lines 65-67). Figure 6 provides a complementary scheme of the synthesis.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-6 remain rejected under 35 U.S.C. 103(a) as being unpatentable over MOSBACH, as applied to claims 1-3, 5 and 6, *supra*.

The instant claims are presented *supra*, and are further drawn to various peptides useable in the method.

Applicant has not argued the position of the rejection being based upon Applicant's admission of record. Applicant asserts that the method of Mossbach is expensive, and 'unfeasible' for some targets. Applicant asserts that the instant method is more cost effective and provides various benefits. Respectfully, the aspects to which Applicant directs the arguments are anticipated, and thus cannot be overcome by arguments of unobviousness. Further, the aspect to which the obviousness rejection is directed has already been admitted by Applicant to be patentably indistinct from any other peptide or monomer mixture used.

Mosbach teaches the method for is usable for enzymes, antigens, and antibodies (e.g. claim 17).

Because Applicant has admitted on the record that there is no patentable distinction between the peptide epitope of claim 2 and the species recited in claim 4, it would have been obvious to have used any peptide, including those recited, in practicing the method. Additionally, because Applicant has admitted that the method is patentable “irrespective of the support used” and “irrespective of the [monomer] mixture used”, , it would have been obvious to have used any monomer mixture and any support, including those recited, in practicing the method. One would have been motivated to use any peptide, as Applicant has stated that there is no patentable distinction, and because Mosbach teaches you can use any peptide. One would have been motivated to use any support and monomer mixture, as Applicant has stated that there is no patentable distinction, and because Mosbach teaches using monomers and supports. One would have a reasonable expectation for success in practicing the method, as MIP synthesis is widely practiced in the art, and Applicant states that the method can be practiced with any peptide, support and monomer mixture because they are not patentably distinct from one another.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976). In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a). From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

This application contains claims 7-9 drawn to an invention nonelected without traverse in the reply filed on October 7, 2005 (and on July 6, 2005). A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew D. Kosar whose telephone number is (571)272-0913. The examiner can normally be reached on Monday - Friday 08:00 - 16:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia J. Tsang can be reached on (571)272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Andrew D Kosar/

Primary Examiner, Art Unit 1654